Brief Report

A clinically meaningful training effect in walking speed using functional electrical stimulation for motor-incomplete spinal cord injury

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Context/Objective: The study aimed to investigate the presence of a training effect for rehabilitation of walking function in motor-incomplete spinal cord injury (SCI) through daily use of functional electrical stimulation (FES).
Setting: A specialist FES outpatient centre.
Participants: Thirty-five participants (mean age 53, SD 15, range 18-80; mean years since diagnosis 9, range 5 months - 39 years) with drop foot and motor-incomplete SCI (T12 or higher, ASIA Impairment Scale C and D) able to ambulate 10 metres with the use of a walking stick or frame.
Interventions: FES of the peroneal nerve, glutei and hamstrings as clinically indicated over six months in the community.
Outcome Measures: The data was analysed for a training effect (difference between unassisted ten metre walking speed at baseline and after six months) and orthotic effects (difference between walking speed with and without FES) initially on day one and after six months. The data was further analysed for a minimum clinically important difference (MCID) (>0.06 m/s).
Results: A clinically meaningful, significant change was observed for initial orthotic effect (0.13m/s, CI: 0.04-0.17, P = 0.013), total orthotic effect (0.11m/s, CI: 0.04-0.18, P = 0.017) and training effect (0.09m/s, CI: 0.02-0.16, P = 0.025).
Conclusion: The results suggest that daily independent use of FES may produce clinically meaningful changes in walking speed which are significant for motor-incomplete SCI. Further research exploring the mechanism for the presence of a training effect may be beneficial in targeting therapies for future rehabilitation.

Keywords: Spinal cord injury, Functional electrical stimulation, Peroneal nerve stimulation, Training effect

Introduction

In the UK there is a prevalence of 40,000 people living with a traumatic spinal cord injury (SCI), with approximately 1100-1200 new cases per year.[1] In the US, there is a prevalence of 270,000 people, with approximately 17,000 people sustaining a SCI every year.[2] It is estimated that 50% of SCI is incomplete[3] and the number of people with incomplete SCI relative to complete is steadily increasing.[4] Despite a positive prognosis for many people with motor-incomplete SCI returning to a level of functional walking,[5] a number of limitations with walking ability may persist leading to a greater risk of falls, a decreased ability to engage in the community and likelihood of injury.[6] A number of studies have suggested that interventions for walking may enable improvement after a motor-incomplete SCI due to the processes of neuroplasticity.[7] Functional electrical stimulation (FES) of the lower limb is one potential technique that has been used to promote gait restoration for people with motor-complete SCI.

A 'therapeutic' or 'training' effect is used in the FES literature to describe an enduring improvement in function following the use of an assistive device.[8–11] A training effect may be measured as an improvement in unassisted walking speed after a period of weeks or months of using

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the device compared to day one. In contrast, an 'orthotic effect' may be used to describe the immediate improvement in walking speed observed while using the device compared to unassisted walking. One of the first studies to assess the long term effectiveness of using FES as a daily orthotic aid for motor-incomplete SCI (n=31), examined the effectiveness of using FES over the period of a year. Researchers used a mixture of stimulation devices of between one and four channels.[12] The majority of devices were operated through using a hand switch to turn stimulation on and off (n=22), which was not the most practical way of activating the stimulation. To explore the use of alternative ways of triggering stimulation, the remaining nine participants were provided with a device which had the option of using a hand switch to trigger stimulation, a footswitch or a tilt sensor. In recent years advancements in FES technology have led to the use of footswitches and tilt sensors which have contributed to devices being more practical and user friendly. Increased consideration of usability factors has increased reliability and accessibility to the technology. Researchers found a significant difference in orthotic speed of walking, with encouragingly large improvements for some participants in terms of a training effect in walking speed. Overall however, the results for a training effect were less clear, with a lot of variability in the values.[12]

Following an initial interest in using FES in the community as a daily orthotic aid, subsequent studies have focused on attempting to maximise a training effect from using FES combined with other technologies, such as body-weight-assisted treadmill training. Studies combining FES with other technologies conducted in a lab or clinic setting have mostly been supportive of a training effect.[8–11] They also have the advantage of being more inclusive of a broader ability range of participant. In one randomised controlled trial (RCT), which focused on chronic incomplete SCI (n=74) (American Spinal Injury Association Impairment Scale (AIS) C or D injury),[10] researchers hypothesised that treadmill based training combined with FES, would be the most effective compared to three other interventions. The interventions included over ground training with FES, treadmill based training with manual assistance and treadmill based training with robotic assistance. Participants were treated five days per week, over a period of 12 weeks. Interestingly, researchers found a training effect in walking speed for both over-ground training with FES and treadmill based training with FES, but over-ground training improved to the greatest extent for distance.[10] The authors note that over-ground training requires patients to practice initiating stepping which contrasts with treadmill walking where step initiation is facilitated. The results suggest that future interventions would benefit from targeting over-ground walking in a real life setting.

A systematic review comparing different interventions to identify a superior treatment for gaining a training effect was found to be inconclusive.[3] The review included five RCTs which examined treadmill training with and without bodyweight support, robotic-assisted gait training and electrical stimulation. Due to the lack of available evidence, authors were unable to conclude as to the superiority of any technique.[3] Instead of attempting to identify a superior treatment, it may be preferable to identify and optimise factors associated with the processes of neuroplasticity such as task specificity and forced re-use of the limb,[7] regardless of the treatment. Task specificity advocates that it is more effective to directly practice the skill that you would like to improve. Forced re-use is a term used to describe the minimisation of compensation strategies and progressive challenging of patients in order to induce adaptation of the behavior.[7]

For motor incomplete SCI patients that are ambulatory, an intervention that can be incorporated into daily living and be used independently such as FES, presents some practical advantages over more complex interventions. FES used as a daily orthotic device has the advantage of being task specific in facilitating walking in the home and the community. Despite clear practical advantages, FES may be limited in other areas which are associated with promoting gait improvement such as forced re-use of the limb. Although FES promotes a healthy gait pattern, used as a daily orthotic aid, it may over-compensate and limit the adaptive capacity of the walking behavior.[7] A study exploring the effect of using FES as a daily orthotic aid to promote a training effect would provide greater insight into the effectiveness and potential limitations of this technique.

The majority of studies conducted have focused on intensive, task specific treatment over a number of sessions a week to maximise a training effect.[8–11] In contrast, the current paper focuses on the effectiveness of a simple FES device that can be used independently on a daily basis. The study will include people with motor incomplete SCI that are ambulatory through the use of a walking stick or frame. The advantage of a device that can be used independently, is the potential to maximise the intensity of the treatment in a task specific environment. The findings from studies conducted in the area, could be used to suggest that increased intensity of the intervention[8–11] through independent daily use,[12] is likely to lead to therapeutic improvements rather than a deterioration in walking

due to dependency. Therefore, it is hypothesised that providing participants with the opportunity for daily independent use of FES over a six month period, will lead to a significant training effect in walking speed.

Method

Thirty-five participants (mean age 53, SD 15, range 18-80; mean years since diagnosis: 9; range: 5 months to 39 years) with motor-incomplete spinal cord injury and drop foot (neurological level of injury T12 or higher, ASIA impairment scale (AIS) C and D) formed a referred sample for treatment. Out of 35 participants, three were referred for bilateral treatment. Study exclusion criteria consisted of the inability to walk 10 metres with the assistance of a walking aid (i.e. stick or frame), poorly controlled epilepsy and fixed skeletal deformities. Those with a cardiac pacemaker, implanted defibrillator or other active implanted device were investigated by a cardiac technician to ensure no interaction with FES. Other exclusions included recent injury which involved damaged skin, fracture or surgery, major skin conditions and the proximity of cancerous tissue to the site of stimulation. A sample of convenience was used in the study with participants being referred for treatment on an outpatient basis by either general practitioners or hospital consultants, with the majority being funded by the United Kingdom's National Health Service. Patients were referred for bilateral or unilateral FES treatment. The FES clinician decided whether treatment was indicated for one or both limbs. The assessment was based on the severity of the presentation of both limbs. The criteria used to make this assessment primarily focused on safety through examining the amount of dorsiflexion, heel strike and foot clearance of the less impaired limb with a focus on safety. The clinician also considered 10 metre walking speed.

Clinical procedure

After an initial assessment to determine whether FES was a suitable treatment to be used as a daily walking aid, patients were invited to return for a set-up appointment. All participants used an FES drop foot stimulator (ODFS Pace ®, Odstock Medical, Salisbury UK). The devices stimulated at 40Hz using either a symmetrical or asymmetrical biphasic waveform, with current intensity up to 100mA and pulse width up to 360 microseconds. Stimulation, intensity, waveform, and timing parameters were adjusted to optimize the correction of drop foot for each individual. At the set-up appointment suitable muscles were stimulated to provide the optimum walking function for each individual: (a) stimulation to the dorsiflexors for a single dropped foot application; (b) a combination of common peroneal nerve stimulation to supply the dorsiflexors and hamstring stimulation to assist with knee flexion during the swing phase of gait; (c) peroneal nerve stimulation combined with gluteal muscle stimulation, to assist with hip extension on the stance phase of gait, to provide support with weight bearing and an upright posture; (d) bilateral dorsiflexion stimulation was also available.

Participants were instructed on how to use the FES equipment for daily independent use. Stimulation was timed to the swing phase of gait using a foot switch under the heel. Participants were instructed to gradually introduce the device into their everyday walking to become accustomed to the stimulation. They were also encouraged to use the device whenever they felt it would assist their walking. No further instructions were given as to the duration and frequency with which participants should use their device. Participants completed 10 metre walking speed measures at baseline and after six months. Four walks were completed on each occasion including a warm up walk with FES turned off, a walk with FES off, a further walk with FES on and a final walk with FES off. The methodology has been used in a previous study to be inclusive of more impaired patients.[13]

As the data was collected as part of routine clinical audit, formal National Health Service (NHS) ethical approval through committee was not required to use the data. This is consistent with guidelines that have been developed to enable the differentiation between research, clinical audit and service evaluation in the UK.[14] The study was conducted following the guidelines of the declaration of Helsinki. Patients included in the study provided consent for the storage and use of their data for the purposes of audit and publication. Statistical analysis was completed using NCSS 10. The data was explored using histograms and box plots and found to be from a normal distribution. Planned comparisons were conducted using paired two-tailed t-tests. A significance level of $P<0.05$ was used. The data was analysed for a training effect (difference between unassisted walking at baseline and after six months), an initial orthotic effect (difference between unassisted walking and FES on day one), a continuing orthotic effect (difference between unassisted walking and walking with FES after six months) and a total orthotic effect (difference between unassisted walking at baseline and walking with FES after six months) which was further analysed for minimum clinically important differences (MCID) (>0.06 m/s).[15] A

Holm-Bonferroni was used to adjust for multiple comparisons.

Results

All participants received FES treatment to one limb including patients who had been referred for bilateral treatment. Fig. 1 displays the flow of participants through the study. Thirty-five people started FES treatment, seven participants were discharged from treatment due to: a deterioration in function (2), declining treatment (3), sensitive to stimulation (1) and one participant was lost to follow-up. Four were excluded from the final analysis as they missed their appointment therefore their measures were not taken, leaving 24 participants for the analysis.

The results for the planned comparisons are displayed in Table 1. A significant and minimal clinically important difference (MCID) was found on day one for initial orthotic effect (0.013m/s, confidence interval (CI): 0.04-0.17, P=0.013). A significant and MCID (0.11m/s, CI: 0.04-0.18, P=0.017) was found for total orthotic effect after six months of using FES. A significant and MCID in training effect was also found (0.09m/s, CI: 0.02-0.16, P=0.025). No significant difference or MCID was found for continuing orthotic effect (0.02m/s, CI:-0.04-0.09, P=0.05).

Discussion

The results from a relatively small sample of participants, suggests that independent, daily home use of FES, may be used to produce significant changes in walking for motor-incomplete SCI which are clinically meaningful. The sample included those with a recently acquired and long term motor incomplete SCI injury, therefore it is particularly encouraging that a significant training effect was achieved. Participants also achieved a significant immediate initial orthotic effect from using stimulation on day one and an overall total orthotic effect after using FES for six months. Interestingly, they did not achieve a significant continuing orthotic effect after six months. A continuing orthotic effect is measured as the difference between unassisted walking and walking with FES after six months. An improvement in training effect is measured as the difference in walking speed of unassisted walking after six months compared to day one. An improvement in training effect is consistent with no significant improvement in continuing orthotic effect, as an improvement in unassisted walking speed may have led to a reduced difference between unassisted and FES assisted walking.

The underlying potential mechanism for the observed training effect is unknown, however, it is well documented that after a SCI there is extensive skeletal muscle atrophy.[16] One potential reason for the observed improvements in training effect is the well documented muscle hypertrophy following the use of cycling FES and neuromuscular electrical stimultion.[17] A future study which measures changes in skeletal muscle attenuation following the use of FES for walking would provide further insight into the underlying mechanism. In addition to muscular hypertrophy, the observed improvement in training effect could also be a temporary carry-over effect. A temporary carry-over effect lasting up to an hour has been observed in stroke[18] and motor incomplete SCI patients.[19] The design for measuring a training effect in the current study did not account for a potential temporary carry-over effect. Further work examining the duration and frequency of a temporary carry-over effect in motor incomplete SCI could be used to inform the design of a study that avoids any potential temporary inflation of results.

Further work should also examine the association between a behavioral temporary carry-over effect in walking, the immediate observed modulation of cortical excitability following the use of electrical stimulation[20] and any long term training or therapeutic effect. Potentially an observed temporary carry-over effect and ability to modulate cortical excitability following the use of electrical stimulation could be predictive of a long term training effect. A further potential mechanism is the reorganisation of intact descending motor circuits to compensate for lost function.[21] The current study is not able to provide any further insight into the likelihood of this being the likely mechanism. Further research which measures spinal cord integrity and residual connectivity prior and after treatment using electrophysiological measures such as transcranial magnetic stimulation (TMS) and imaging measures such as magnetic resonance imaging (MRI) may provide the necessary sensitivity required to detect any changes that may appear following the implementation of interventions such as FES.

Of particular interest in the current study is that participants were instructed to use the FES device as an orthotic aid for daily walking as and when required, rather than specifically for rehabilitation, yet after six months of use this led to a training effect. Therefore, potentially there could be additional benefits if the device is used specifically to target enhancement of a training effect. The study provides a good basis for designing an RCT, which examines the effectiveness of independent, daily home use of FES, in comparison to a control group.

The current study is limited in using a heterogeneous sample in terms of acuity post SCI**.** Furthermore, AIS C

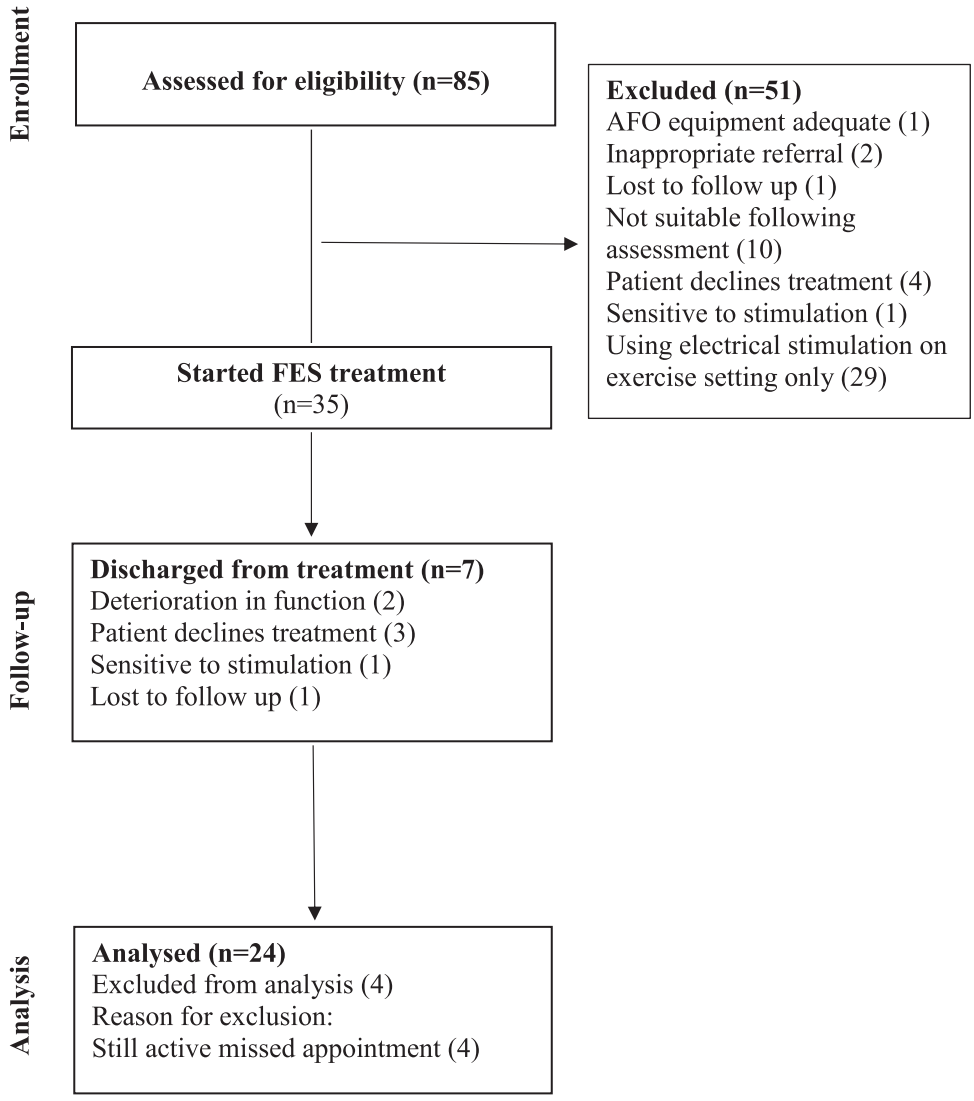

Figure 1 Diagram showing the flow of participants through the study.

and AIS D are generally high functioning individuals especially an AIS D who is only months post SCI has high chances of physiological recovery, so a larger sample or a control group would be needed to draw more decisive conclusions. A further limitation is the study only included people with motor incomplete SCI

Table 1 Mean walking speed (m/s) for incomplete spinal cord injury participants with and without FES (n=24).

	Baseline		After six months						
Planned Comparison	Non FES	FES	Non FES	FES	T value	P	Holm-Bonferroni P Value Correction	Means of the difference	CI (95%)
Initial Orthotic Effect	0.61 (0.30)	0.71 (0.32)			-3.15	0.004	0.013	0.10*	0.04-0.17
Continuing Orthotic Effect			0.69 (0.34)	0.72 (0.33)	-0.79	0.436	0.050	0.02	-0.04-0.09
Total Orthotic Effect	0.61 (0.30)			0.72 (0.33)	-3.11	0.005	0.017	0.11*	0.04-0.18
Training Effect	0.61 (0.30)		0.69 (0.34)		-2.56	0.017	0.025	0.09*	0.02-0.16

CI, confidence intervals.
*Minimal clinically important difference (MCID) = 0.06 m/s[15].

who were able to ambulate 10 metres. This is not necessarily representative of current clinical practice where patients may be provided with neuromuscular electrical stimulation and exercises prior to starting FES for walking to increase their muscular strength. The current study is further limited in not providing a measurement of how frequently participants used the FES device. Further research including an activity monitor and a step counter on the FES device would be useful for exploring the frequency of walking completed with and without FES. It could also be used to examine the dose associated with a training effect. Further research exploring the mechanism for the presence of a training effect may be beneficial in targeting therapies for future rehabilitation. In particular, it would be of value to examine innovative ways that optimize the gains associated with the processes of neuroplasticity, combined with independent, daily home use of FES.

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